Response to Claim Objections

1. In order to correct informalities in claims 1-8, claim 1 of application 10/055,290 is amended to read "1. A collection vessel for collecting and transferring a body fluid specimen comprising: a hollow body having a first end and a second end;

a first seal at said first end;

a plunger disposed within said hollow body between said first end and said second end;

said plunger providing a second seal;

a plunger lock coupled to said plunger;

said plunger lock being configured to selectively maintain said plunger at said second end when at least a portion of said hollow body between said first seal and said second seal is at least partially evacuated;

said plunger lock further configured to release said plunger, thereby allowing said plunger to move toward said first seal within said hollow body.

3. In order to conform to 35 U.S.C. 112, claim 9 of application 10/055,290 is amended to read "9. A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen comprising the steps of: providing a fluid collection needle having a first end and a second end;

providing a sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end, said sterile seal configured wherein said sterile seal is maintained at said open end when at least a portion of said sterile hollow body is at least partially evacuated;

providing a device for collecting a second body fluid specimen comprising a sterile hollow body having and a closed end, a sterile seal at said open end, said sterile seal configured wherein said sterile seal is maintained at said open end when at least a portion of said sterile hollow body is at least partially evacuated;

providing an antiseptic;

preparing a site on a patient's skin for puncture using said antiseptic; piercing said site using said first end of said fluid collection needle;

at least partially filling said sterile evacuated specimen tube with said first body fluid specimen by piercing through said sterile seal of said sterile evacuated specimen tube using said second end of said fluid collection needle such that piercing through said sterile seal of said sterile evacuated specimen tube does not contaminate said second end of said fluid collection needle;

at least partially filling said device for collecting the second body fluid specimen with said second body fluid specimen having fewer living contaminants than said first body fluid specimen by piercing through said sterile seal of said device for collecting said second body fluid specimen using said second end of said fluid collection needle, such that piercing through said sterile seal of said device for collecting said second body fluid specimen does not contaminate said second end of said fluid collection needle and;

selecting said second body fluid specimen for use in a diagnostic test to detect the presence of organisms in said second body fluid specimen.

5. The rejection of claims 9, 13, and 16 of application 10/055,290 under 35 U.S.C 102(b) is being argued against as follows:

Distinction from Theodore A. Golden's patent number 4,676,256

Claims 9 and 13 of application 10/055,290 describe a method for collecting a first and a second body fluid specimen such that the second body fluid specimen has a lower concentration of living contaminants than the first body fluid specimen, using a fluid collection needle having a first and a second end, a sterile evacuated specimen tube, and a device for collecting a second body fluid specimen. This method was developed in order to allow the collection of at least the second body fluid specimen, and likely a third subsequent body fluid specimen, in a manner that makes it more suitable for a diagnostic test for the detection of the presence of microorganisms than what is provided by methods of the prior art.

The described manufactures and method of claims 9 and 13 accomplish this by controlling three key variables. First, contaminant material passing into the first end of the fluid collection needle upon venepuncture, comprising mainly skin and commensal microorganisms, is collected into the sterile evacuated specimen tube along with the first body fluid specimen. Second, the second end of the fluid collection needle avoids contamination from the sterile evacuated specimen tube due to the sterile state of the seal maintained at the open end of the sterile evacuated specimen tube. Third, the second end of the fluid collection needle avoids contamination from the device for collecting a second body fluid specimen due to the sterile state of the sterile seal maintained at the open end of the device. This third control prevents not only the contamination of the second body fluid specimen as the second end of the fluid collection needle passes through the sterile seal of the device for collecting a second body fluid specimen, but also maintains the sterile state of the second end of the fluid collection needle in order that an

additional third body fluid specimen or plurality of body fluid specimens having a lower concentration of contaminants than the first body fluid specimen can be further collected. It is only when all three variables are controlled that the second body fluid specimen is made more suitable for a diagnostic test for the presence of microorganisms than the first body fluid specimen.

The devices described in Golden's patent 4,676,256 comprise a hypodermic needle having an end to be "inserted into a patient's vein" and a plurality of upstanding needles oriented such that "downward movement of the vacuum tube also displaces or pushes the resilient plug downwardly toward the bottom of the socket, thereby permitting blood to flow into the vacuum tube through the upstanding needle." In studying the specifications of Golden's patent 4,676,256, it does appear reasonable that the described devices could be used in order to prevent contamination between collected blood samples. In this case, a method for collecting a first and a second body fluid specimen such that the second body fluid specimen has a lower concentration of contaminants than the first body fluid specimen, could avoid the need for the sterile seal on the sterile evacuated specimen tube if the first and the second body fluid specimens are collected on separate upstanding needles. However, if Golden's patent 4,676,256 is implemented in order to collect the first and the second body fluid specimen without further instruction, it remains equally likely that either body fluid specimen would be used in a diagnostic test for the detection of the presence of microorganisms. Thus, the first body fluid specimen having a higher concentration of living contaminants would be used in a diagnostic test for the detection of the presence of microorganisms as often as the second body fluid specimen, which is more suitable for such testing.

When combined with the teachings of the prior art, the situation is dramatically worsened. In the field of blood collection, the standard set forth by the National Committee for Clinical Laboratory Standards (NCCLS) for collecting blood specimens for culturing using a mutliple-sampling needle having a first and a second end dictates that a blood specimen for culturing be drawn before any other blood specimen as this is perceived as the most suitable blood specimen for culturing [1]. This standard is universally endorsed by other authorities in the field such as the Center for Phlebotomy Education (CPE) and the American Society for Phlebotomy Technicians (ASPT). Many health care providers have readily adopted this standard as policy [2,3,4,5,6], and there is no known deviation from this standard in practice. If Golden's patent 4,676,256 is implemented with the teachings of the prior art, it is very likely that the standard would remain intact for these devices as well. Thus, the first blood specimen using Golden's devices would more likely be the blood specimen selected for culturing when used by one skilled in the art.

Claims 9 and 13 of application 10/055,290 absolutely require that the first body fluid specimen be collected prior to the collection of the second body fluid specimen in order to prevent the entry of venepucture-derived contaminants into the second body fluid specimen. Additionally, in the prior art, with or without Golden's patent 4,676,256, when the only blood specimen needed for testing is the blood specimen for culturing no other blood specimens are collected. When claims 9 and 13 of application 10/055,290 are implemented in the collection of blood specimens for culturing, collection of a first blood specimen prior to a second blood specimen for culturing is necessary. This is in direct

opposition to the prior art and is believed to be unanticipated by Golden's patent 4,676,256.

Claim 16 of application 10/055,290 describes a kit that facilitates the execution of the methods of claims 9 and 13. The kit of claim 16 allows the sterile evacuated tube for collecting the first body fluid specimen and the device for collecting the second body fluid to be packaged such that the sterile evacuated tube and the device for collecting the second body fluid specimen maintain sterility on their external surfaces. This sterility is necessary in order to prevent contamination of the second end of the fluid collection needle when the sterile evacuated specimen tube and the device for collecting the second body fluid specimen are used as is described in claims 9 and 13. The kit of claim 16 also ensures that the sterile specimen tube and the device for collecting the second body fluid specimen are used together in a method consistent with claims 9 and 13. Golden's patent 4,676,256 does not appear to describe or anticipate the assembly of such a kit, nor does it suggest a method for using the contents of the kit.

7. The rejection of claims 10 and 11 of application 10/055,290 under 35 U.S.C 103(a) is being argued against as follows:

Claims 10 and 11 are claims dependent on the method for collecting a first and a second body fluid specimen, the second body fluid specimen having a lower concentration of living contaminants than the first body fluid specimen claimed in claim 9. Claim 9 requires that the second body fluid specimen be used in a diagnostic test for the detection of the presence of organisms. One of the diagnostic tests best known in the current art for detecting the presence of organisms is a blood culture. In the current art,

the blood culture requires a blood specimen that is directly drawn directly into a blood culture bottle, collected into an evacuated specimen tube having an additive of sodium polyanethole sulfonate (SPS), or collected into a syringe. In the latter two methods, the blood sample must be further transferred into the blood culture bottle for testing. Claims 10 and 11 claim the blood culture bottle and the specimen tube having a SPS additive as a device for collecting a second body fluid specimen within the limits of their use in the method of claim 9.

While it is agreed that it is obvious that Golden's patent 4,676,256 could be implemented in order to collect a blood sample into a blood culture bottle or an evacuated specimen tube having an SPS additive, it is believed that one skilled in the art would consistently choose to collect a first blood sample into the blood culture bottle or the evacuated specimen tube having an SPS additive. The reasoning upon which this prediction is based is described in point 5 of this response to office actions on application 10/055,290.

Additional amendments to application 10/055,290

In order to correct informalities, Claim 2 of application 10/055,290 is amended to read:

2. A collection vessel for collecting and transferring a body fluid specimen according to claim 1, further comprising:

an airtight junction that interrupts said hollow body forming a first section and a second section;

said first section having said first seal;

said second section having said plunger and said plunger lock;

said airtight junction configured to allow for separation of said first section and said second section and coupling of a transfer needle to said second section.

In order to correct informalities, claim 5 of application 10/055,290 is amended to read:

5. A collection vessel for collecting and transferring a body fluid specimen according to claim 1, wherein said plunger lock breaks away from said plunger, thereby allowing said plunger to move towards said first seal within said hollow body.

In order to correct informalities, claim 7 of application 10/055,290 is amended to read:

7. A collection vessel for collecting and transferring a body fluid specimen according to claim 1, further comprising an additive within said collection vessel.

In order to correct informalities, claim 8 of application 10/055,290 is amended to read:

8 . A collection vessel for collecting and transferring a body fluid specimen according to claim 1, wherein said collection vessel is sterilized and packaged to maintain sterility.

In order to correct informalities, claim 9 of application 10/055,290 is amended to read:

9. A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen comprising the steps of: providing a fluid collection needle having a first end and a second end;

providing a sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end of said sterile evacuated specimen tube, said sterile seal of said sterile evacuated specimen tube configured wherein said sterile seal of said sterile evacuated specimen tube is maintained at said open end of said sterile evacuated specimen tube when at least a portion of said sterile hollow body of said sterile evacuated specimen tube is at least partially evacuated;

providing a device for collecting a second body fluid specimen comprising a sterile hollow body having an open end, a sterile seal at said open end of said device for collecting a second body fluid specimen, said sterile seal of said device for collecting a second body fluid specimen configured wherein said sterile seal of said device for collecting a second body fluid specimen is maintained at said open end of said device for collecting a second body fluid specimen when at least a portion of said sterile hollow body of said device for collecting a second body fluid specimen is at least partially evacuated;

providing an antiseptic;

preparing a site on a patient's skin for puncture using said antiseptic; piercing said site using said first end of said fluid collection needle;

at least partially filling said sterile evacuated specimen tube with said first body fluid specimen by piercing through said sterile seal of said sterile evacuated specimen tube using said second end of said fluid collection needle such that piercing through said sterile seal of said sterile evacuated specimen tube does not contaminate said second end of said fluid collection needle;

at least partially filling said device for collecting a second body fluid specimen with said second body fluid specimen having fewer living contaminants than said first body fluid specimen by piercing through said sterile seal of said device for collecting a second body fluid specimen using said second end of said fluid collection needle, such that piercing through said sterile seal of said device for collecting a second body fluid specimen does not contaminate said second end of said fluid collection needle and;
selecting said second body fluid specimen for use in a diagnostic test to detect the presence of organisms in said second body fluid specimen.

In order to correct informalities, claim 10 of application 10/055,290 is amended to read:
10. A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen according to claim 9, wherein said device for collecting a second body fluid specimen is an evacuated culture vessel further comprising a liquid media contained within said sterile hollow body of said device for collecting a second body fluid specimen.

In order to correct informalities, claim 11 of application 10/055,290 is amended to read:
11. A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen according to claim 9, wherein said device for collecting a second body fluid specimen is an evacuated specimen tube further

comprising an additive of sodium polyanethole sulfonate within said sterile hollow body of said device for collecting a second body fluid specimen.

In order to correct informalities, claim 12 of application 10/055,290 is amended to read:

12. A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen according to claim 9, wherein said device for collecting said second body fluid specimen is a collection vessel further comprising:

said sterile hollow body of said device for collecting said second body fluid specimen having a second end;

a plunger disposed within said sterile hollow body of said device for collecting a second body fluid specimen between said open end of said device for collecting a second body fluid specimen and said second end;

said plunger sealing said sterile hollow body of said device for collecting a second body fluid specimen;

a plunger lock coupled to said plunger;

said plunger lock being configured to selectively maintain said plunger at said second end when at least a portion of said sterile hollow body of said device for collecting a second body fluid specimen between said sterile seal of said device for collecting a second body fluid specimen and said plunger is at least partially evacuated;

said plunger lock further configured to release said plunger, thereby allowing said plunger to move toward said sterile seal of said device for collecting a second body fluid specimen within said sterile hollow body of said device for collecting a second body fluid specimen.

In order to correct informalities, claim 13 of application 10/055,290 is amended to read:

13. A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen comprising the steps of:

providing a fluid collection needle having a first end and a second end and a tube between said first end and said second end;

providing a sterile evacuated specimen tube comprising a hollow body having an open end, a sterile seal at said open end of said sterile evacuated specimen tube, said sterile seal of said sterile evacuated specimen tube configured wherein said sterile seal of said sterile evacuated specimen tube is at said open end of said sterile evacuated specimen tube and said hollow body of said sterile evacuated specimen tube is at least partially evacuated, and configured wherein said sterile evacuated specimen tube is sterilized and packaged to maintain sterility;

providing an evacuated culture vessel comprising a hollow body having an open end, a sterile seal at said open end of said evacuated culture vessel, a liquid media within said hollow body of said evacuated culture vessel, configured wherein said hollow body of said evacuated culture vessel is at least partially evacuated;

providing an antiseptic;

preparing a site on a patient's skin for puncture using said antiseptic;

piercing said site on a patient's skin using said first end of said fluid collection needle;

at least partially filling said sterile evacuated specimen tube with said first body fluid specimen by piercing through said sterile seal of said sterile evacuated specimen tube using said second end of said fluid collection needle;

at least partially filling said evacuated culture vessel with said second body fluid specimen by piercing through said sterile seal of said evacuated culture vessel with said second end of said fluid collection needle;

using said evacuated culture vessel having said second body fluid specimen for a diagnostic test to detect the presence of organisms in said second body fluid specimen.

In order to correct informalities, claim 14 of application 10/055,290 is amended to read:

14. A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen comprising the steps of:

providing a fluid collection needle having a first end and a second end and a tube between said first end and said second end;

providing a first sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end of said first sterile evacuated specimen tube, said sterile seal of said first sterile evacuated specimen tube configured wherein said sterile seal of said first sterile evacuated specimen tube is maintained at said open end of said first sterile evacuated specimen tube when at least a portion of said sterile hollow body of said first sterile evacuated specimen tube is at least partially evacuated;

providing a second sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end of said second sterile evacuated specimen tube, an additive of sodium polyanetholesulfonate within said sterile hollow body of said second sterile evacuated specimen tube, said sterile seal of said second sterile evacuated specimen tube configured wherein said sterile seal of said second sterile evacuated specimen tube is maintained at said open end of said second sterile evacuated specimen tube when at least a portion of said sterile hollow body of said second sterile evacuated specimen tube is at least partially evacuated;

providing an antiseptic;

providing a transfer device comprising a syringe having a hollow body and a plunger and a transfer needle, said syringe and said transfer needle configured wherein pulling back on said plunger allows a movement of fluid into said syringe through said transfer needle;

providing an evacuated culture vessel comprising a hollow body having an open end, a sterile seal at said open end of said evacuated culture vessel, a liquid media within said hollow body of said evacuated culture vessel, configured wherein said hollow body of said evacuated culture vessel is at least partially evacuated;

preparing a site on a patient's skin for puncture using said antiseptic;

piercing said site on a patient's skin using said first end of said fluid collection needle;

at least partially filling said first sterile evacuated specimen tube with said first body fluid specimen by piercing through said sterile seal of said first sterile evacuated specimen tube using said second end of said fluid collection needle, such that said second end of said fluid collection needle is not contaminated by said sterile seal of said first sterile evacuated specimen tube;

at least partially filling said second sterile evacuated specimen tube with said second body fluid specimen by piercing through said sterile seal of said second sterile evacuated specimen tube using said second end of said fluid collection needle, such that said second end of said fluid collection needle is not contaminated by said sterile seal of said second sterile evacuated specimen tube;

transferring said second body fluid specimen to said evacuated culture vessel and;

using said evacuated culture vessel having said second body fluid specimen for a diagnostic test to detect the presence of organisms in said second body fluid specimen.

In order to correct informalities, claim 15 of application 10/055,290 is amended to read:

15. A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen comprising the steps of:

providing a fluid collection needle comprising a cannula having a first end and a second end,

providing a sterile evacuated specimen tube comprising; a sterile hollow body having an open end, a sterile seal at said open end, said sterile seal configured wherein said sterile seal is maintained at said open end when at least a portion of said sterile hollow body is at least partially evacuated;

providing a sterile collection vessel for collecting and transferring a body fluid specimen comprising a hollow body having a first end and a second end,

a first seal at said first end,

a plunger disposed within said hollow body between said first end and said second end,

said plunger providing a second seal,

a plunger lock coupled to said plunger,

said plunger lock being configured to selectively maintain said plunger at said second end when at least a portion of said hollow body between said first seal and said second seal is at least partially evacuated,

said plunger lock can further be configured to release said plunger thereby allowing said plunger to move toward said first seal within said hollow body;

providing an antiseptic;

providing a transfer device comprising a cannula having a first end and a second end, said first end of said transfer device protected by a first needle shield, said second end of said transfer device protected by a second needle shield;

providing an evacuated culture vessel comprising a hollow body having an open end, a sterile seal at said open end of said evacuated culture vessel, a liquid media within said hollow body of said evacuated culture vessel, configured wherein said hollow body of said evacuated culture vessel is at least partially evacuated;

preparing a site on a patient's skin for puncture using said antiseptic;

piercing said site on a patient's skin using said first end of said fluid collection needle;

at least partially filling said sterile evacuated specimen tube with said first body fluid specimen by piercing through said sterile seal of said sterile evacuated specimen tube using said second end of said fluid collection needle, such that said second end of said fluid collection needle is not contaminated by said sterile seal of said sterile evacuated specimen tube;

at least partially filling said collection vessel with said second body fluid specimen by piercing through said first seal of said collection vessel using said second end of said fluid collection needle, such that said second end of said fluid collection needle is not contaminated by said first seal of said collection vessel;

configuring said plunger lock to release said plunger;

piercing through said first seal of said collection vessel using said first end of said transfer device; piercing through said sterile seal of said evacuated culture vessel, such that said second body fluid specimen flows into said evacuated culture vessel and;

using said evacuated culture vessel having said second body fluid specimen for a diagnostic test to detect the presence of organisms in said second body fluid specimen.

In order to correct informalities, claim 16 of application 10/055,290 is amended to read:

16. A kit for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen said kit comprising:

a sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end of said sterile evacuated specimen tube, said sterile hollow body of said sterile evacuated specimen tube configured wherein said sterile seal of said sterile evacuated specimen tube is at said open end of said sterile evacuated specimen tube and a portion of said sterile hollow body of said sterile evacuated specimen tube is at least partially evacuated and;

a device for collecting a second body fluid specimen comprising a sterile hollow body having an open end, a sterile seal at said open end of said device for collecting a second

body fluid specimen, said sterile seal configured wherein said sterile seal of said device for collecting a second body fluid specimen is maintained at said open end of said device for collecting a second body fluid specimen when at least a portion of said sterile hollow body of said device for collecting a second body fluid specimen is at least partially evacuated.

In order to correct informalities, claim 17 of application 10/055,290 is amended to read:

17. A kit for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen said kit comprising:

a sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end of said sterile evacuated specimen tube, said sterile seal of said sterile evacuated specimen tube configured wherein said sterile seal of said sterile evacuated specimen tube is maintained at said open end of said sterile evacuated specimen tube when at least a portion of said sterile hollow body of said sterile evacuated specimen tube is at least partially evacuated and;

an evacuated culture vessel comprising a hollow body having an open end, a sterile seal at said open end of said evacuated culture vessel, a liquid media within said hollow body of said evacuated culture vessel, configured wherein said hollow body of said evacuated culture vessel is at least partially evacuated.

In order to correct informalities, claim 18 of application 10/055,290 is amended to read:

18. A kit for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen said kit comprising:
a first sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end of said first sterile evacuated specimen tube, said sterile seal of said first sterile evacuated specimen tube configured wherein said sterile seal of said first sterile evacuated specimen tube is maintained at said open end of said first sterile evacuated specimen tube when at least a portion of said sterile hollow body of said first sterile evacuated specimen tube is at least partially evacuated and;
a second sterile evacuated specimen tube comprising a hollow body having an open end, a sterile seal at said open end of said second sterile evacuated specimen tube, an additive of sodium polyanetholesulfonate within said hollow body of said second sterile evacuated specimen tube, configured wherein said sterile seal of said second sterile evacuated specimen tube is at said open end of said second sterile evacuated specimen tube and said hollow body of said second sterile evacuated specimen tube is at least partially evacuated.

In order to correct informalities, claim 19 of application 10/055,290 is amended to read:
19. A kit for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen said kit comprising:
a sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end, said sterile seal configured wherein said sterile seal is

maintained at said open end when at least a portion of said sterile hollow body is at least partially evacuated and;

a collection vessel comprising a hollow body having a first end and a second end,

a first seal at said first end,

a plunger disposed within said hollow body between said first end and said second end,

said plunger providing a second seal,

a plunger lock coupled to said plunger,

said plunger lock being configured to selectively maintain said plunger at said second end when at least a portion of said hollow body between said first seal and said second seal is at least partially evacuated,

said plunger lock further configured to release said plunger thereby allowing said plunger to move toward said first seal within said hollow body.

In order to correct informalities, claim 20 of application 10/055,290 is amended to read:

20. A method for collecting a first blood specimen and a second blood specimen, said second blood specimen having a lower concentration of living contaminants than said first blood specimen comprising the steps of:

providing a blood collection needle having a first end and a second end;

providing a collection kit comprising a sterile evacuated specimen tube having a sterile hollow body having an open end, a sterile seal at said open end of said sterile evacuated specimen tube, said sterile seal of said sterile evacuated specimen tube configured wherein said sterile seal of said sterile evacuated specimen tube is maintained at said

open end of said sterile evacuated specimen tube when at least a portion of said sterile hollow body of said sterile evacuated specimen tube is at least partially evacuated and

a collection vessel comprising a hollow body having a first end and second end,

a first seal at said first end of said collection vessel,

a plunger disposed within said hollow body of said collection vessel between said first end of said collection vessel and said second end of said collection vessel,

said plunger providing a second seal,

a plunger lock coupled to said plunger,

said plunger lock being configured to selectively maintain said plunger at said second end of said collection vessel when at least a portion of said hollow body of said collection vessel between said first seal and said second seal is at least partially evacuated,

said plunger lock further configured to release said plunger thereby allowing said plunger to move toward said first seal within said hollow body of said collection vessel;

providing an antiseptic;

providing a transfer device comprising a cannula having a first end and second end, said first end of said transfer device protected by a first needle shield, said second end of said transfer device protected by a second needle shield;

providing an evacuated culture vessel comprising a hollow body having an open end, a sterile seal at said open end of said evacuated culture vessel, a liquid media within said hollow body of said evacuated culture vessel, configured wherein said hollow body of said evacuated culture vessel is at least partially evacuated;

opening said collection kit;

preparing a site on a patient's skin for puncture using said antiseptic;

piercing said site on a patient's skin using said first end of said blood collection needle;

at least partially filling said sterile evacuated specimen tube with said first blood specimen by piercing through said sterile seal of said sterile evacuated specimen tube using said second end of said blood collection needle, such that said second end of said blood collection needle is not contaminated by said sterile seal of said sterile evacuated specimen tube;

at least partially filling said collection vessel with said second blood specimen by piercing through said first seal of said collection vessel using said second end of said blood collection needle, such that said second end of said fluid collection needle is not contaminated by said first seal of said collection vessel;

configuring said plunger lock to release said plunger;

piercing through said first seal of said collection vessel using said first end of said transfer device; piercing through said sterile seal of said evacuated culture vessel, such that said second blood specimen flows into said evacuated culture vessel and;

using said evacuated culture vessel having said second blood specimen for a diagnostic test to detect the presence of organisms in said second blood specimen.

References

1. NCCLS Guidelines, "Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture"; Approved Standard-Fourth Edition. H3-A4, June 1998
2. Calgary Laboratory Services, "Blood Collection Tubes / Order of Draw"; Calgary Laboratory Services website.
3. Happel, Julie Paulson, "Suggested Order of Draw Using an Evacuated Tube System and Order of Transfer from Syringe to Sample Tubes"; Virtual Hosptial website.
4. Alliance Laboratory Services, "Order of Draw for Blood Specimens"; Alliance Laboratory Services website.
5. Phlebotomy West, "Order of Draw – Facts and Controversies"; Phlebotomy West website.
6. UK Hospital Laboratory, "General Lab Information"; http://www.hosp.uky.edu/ClinLab/GENERAL%20LAB%20INFORMATION%208-03.pdf

GENERAL LAB INFORMATION

The UK Hospital Laboratory shall perform tests and examine specimens only on the written request of physicians authorized by the Medical Staff to order such evaluations and receive results. The physician or an authorized representative (i.e., nurse, and clerical staff) must complete the laboratory requisition. This requisition acts as the written order in the laboratory. Testing cannot be performed without it.

Orders or requisitions for inpatient and outpatient services must clearly identify the:

patient (including date of birth and sex)

requesting practitioner in-house (including the physician's identifying code number)

test required and special handling

date and time the specimen was collected

initials of the collector

signs, symptoms or diagnosis

Microbiology requests for antibiotic therapies

Requisitions without this information will be returned. Only in emergency situations will the laboratory analyze a specimen with an incomplete requisition.

STAT requests must be clearly identified on the physician order form and laboratory requisition. The beeper number or telephone number of the ordering physician must be given.

Laboratory procedures, which are not performed by the University of Kentucky Hospital Laboratory, will be referred to an external laboratory ONLY if the attending staff physician signs the requisition.

Pre-Admission Testing

All testing to be performed upon admission to the hospital will be done once the patient is assigned to and in a bed.

Collection of Specimens (In-Patients)

Appropriate personnel on the floor will collect laboratory specimens. It is the responsibility of the collector to label the specimen container properly. The specimen container must have an affixed numbered label which matches the number on the laboratory requisition for all requests except AM labs. Requisitions for laboratory testing must be complete and accurate. It is the responsibility of the collector of the specimen to write the time of collection and tech code or initials of the individual collecting the specimen on the requisition or the tube. The collector must compare the label to the

patient's arm band. AM labs have printed labels that require the time of collection and tech code number for specimens to be acceptable.

For preparation of blood component therapy by the Blood Bank, specimens with no error in identification (e.g. correctly spelled names) are required. Recollection of an incorrectly labeled specimen is mandatory. Treatment need not be delayed since the patient can be treated with universal donor products. Since these are scarce, such solutions to labeling error should be avoided. PLEASE NOTE that beginning March 21, 1991, notification of the Food and Drug Administration (FDA) has been required in some instances of mislabeled blood bank specimens.

The Phlebotomy Service collects blood specimens for analysis from 4 a.m. until 8 a.m. and can be reached at 323-5431. Specimens collected at other times are collected by the appropriate floor personnel. For full details please see Hospital Policy 08-27, Obtaining Laboratory Specimens, (http://www.hosp.uky.edu/policy/hosppolicy/PDF08/hp08-27.pdf).

Patients must be positively identified by name and hospital number on an identification bracelet affixed to the patient's wrist or ankle prior to collection of any specimen. Phlebotomy personnel will not draw blood samples from patients without an identification bracelet.

Outpatient Collection Station

The main collection station for outpatients is located in E-206 of the Kentucky Clinic and is open from 8am to 6pm Monday through Friday. Phlebotomy in Kentucky Clinic is available from 6-7pm by calling pager #3191.

Collections may be performed in the hospital when the Kentucky Clinic is closed by contacting the Admitting Office (3-5811) who will direct the patient to the designated location for phlebotomy.

Repeat Determinations and Test Additions

Repeat determinations are performed routinely as part of the laboratory's ongoing quality control program. The UK Hospital Laboratories will repeat a test when requested by the attending physician. Many specimens will be retained for up to 7 days. The individual laboratories can arrange to do additional testing if sufficient specimen volume remains after the initial tests are completed. To request a test addition, contact the individual laboratories for more information. A written order or test requisition must be submitted to the lab for the add-on test.

Specimen Collection Times and Receipt Times:

Collect time:

It is critical for medical and documentation purposes for specimens to have a time of collection provided when sent to the laboratory. The integrity of the results rely on documenting the time the sample was collected. It is the responsibility of the collector to provide the time of specimen collection.

Receipt time:

Receipt time is defined as the time the specimen is received in the laboratory. For the Anatomic Pathology sections of the laboratory, the computer system documents the time the specimen is accessioned. For the Clinical Laboratory sections, the staff accessioning the specimen into the computer will assign the receipt time as the time that the specimen is clocked into Laboratory Central Receiving.

Special Projects

Research studies and clinical projects requiring laboratory services should be discussed with the appropriate laboratory director and coordinated through the Laboratory Administrative Manager and

Blood Collection Procedures

When drawing blood for multiple tests requiring several different types of tubes, the correct **order of draw** is as follows:

blood cultures

plain red top

blue top

gold top

green top

purple top

gray top

yellow top

When drawing for coagulation tests (e.g. PT, PTT), a plain red top tube must be drawn first to eliminate contamination of the specimen by tissue thromboplastin from the site of the needle puncture. All anticoagulated tubes must be inverted 8 - 10 times immediately after drawing.

Minimum adult blood draw volumes are listed under Test Information: (http://www.hosp.uky.edu/ClinLab/pick.asp). Call individual labs for pediatric minimum volumes.

Please note that the following test must be drawn in a **plain red top tube**:

TAU Transferrin (TAUTFN)
Normethsuximide (NMSX)
CH50
Flecainide (FLEC)
Lamotrigine (LAMOT)
Porphyrins, serum total (PORS)
Primidone + Metabolite (PRIM)
Serum Drug Screen (SDS)
Sulfonylurea Screen (SULFS)
Zonisamide (ZONIS)
Cryocrit (CRYO) needs 3 tubes on heel warmer
Cryocrit IFE (IFECRY) needs 3 tubes on heel warmer
Neonatal Alloimm TP (NATP)
Blood Bank testing

Aminoglycoside (Gentamicin, Tobramycin, Amikacin)/Vancomycin Sample Collection:

Aminoglycosides are infused over a 30 minute period. A ***trough*** level is drawn within 30 minutes prior to the dose and a ***peak*** level is drawn at least 30 minutes after the end of the infusion.

Vancomycin is infused over a one hour time period. A ***trough*** level is drawn within 30 minutes prior to the dose and a ***peak*** level is drawn at least one hour after the end of infusion. An accurate collect time MUST be recorded on the requisition for all peak and trough levels.

Pap Test Collection

A Pap test is simple, quick, and painless; it can be done in a doctor's office, a clinic, or a hospital. While a woman lies on an exam table, the clinician inserts a speculum into her vagina to open it. The cervix should be well visualized. To do the test, a sample of cells is taken from in and around the cervix with a spatula, cervical brush and/or broom-type device. The specimen (or smear) is placed on a glass slide and preserved with 95% ethanol available from the laboratory, spray-fixed with commercial fixative, or is rinsed in a vial of fixative, and is sent to a laboratory for examination.

Phlebotomy Supplies:

Materials Management stocks phlebotomy supplies on the floors. The Lab Central Receiving Area maintains a small supply of special tubes that Materials Management does not stock. The following tubes may be picked up in Lab Central Receiving as needed:

Royal blue top tube without EDTA (metal free tubes)

Tan top tube with EDTA (metal free tube)

Routine Urine Specimens:

Specimens for routine urinalysis must be sent to the lab and the test performed within 2 hours of collection unless refrigerated. If specimen has been refrigerated, it should be indicated on the requisition so the specimen will not be rejected.

24 Hour Urine Collection:

Refer to the 24hr Urine Information at http://www.hosp.uky.edu/ClinLab/24urine.htm for collection requirements for each test. Materials Management stocks plain or "no preservative" urine containers on the floors. Urine containers with preservative (e.g. 6M HCl) are to be picked up at the Lab Central Receiving Area, room HA619. For your convenience, the tests are listed on the urine container that may be collected in that particular preservative.

Pneumatic Tube Specimen Transport System

Pneumatic tube stations for sending specimens directly to the Clinical Laboratory (Station 14) are:

Emergency Department	Station 100
OR Central Corridor	Stations 321
Heart OR Station	121
1 ICU Central Corridor	Station 111
Blood Bank Station	160
Labor and Delivery	Station 330
Pharmacy	Station 320
Children's Hospital	Station 141
Pharmacy, Children Hospital	Station 340
NICU & PICU	Station 341

MCC Clinic	Station 210
MCC 2nd	Station 220
MCC 3rd , Pharmacy	Station 230
MCC, Chemo	Station 211
Hemo-Oc Station	212
Breast Care Clinic	Station 223
BMT	Station 231
Outpatient OR	Station 222
2 ICU Central Corridor	Station 221

Training in use of the Pneumatic tube system is available and may be scheduled by contacting Lab Central at 3-5431. Improper use of the system by a particular area may cause that station to be closed. For more detailed instructions, see the Pneumatic Tube User's Guide located at each station.

Preparation for Transport

Each specimen must be clearly identified as described in General Operating Procedures, double bagged in ziplock bags, placed in a pneumatic tube carrier (with liner) along with the completed laboratory requisition. The requisition should not be inside the ziplock bag.

Lab Central Receiving will take out of service any tube carrier in need of repair (e.g. loose carpet) and replace it with a new one. Each station is responsible for accounting for their four tubes they have been issued.

Specimens that should NOT be sent through the pneumatic tube system are (1) CSF, (2) biopsy or frozen tissue sections, (3) cytology specimens, (4) products of conception, (5) legal specimens, (6) parapak stools, (7) body tissues and organs or (8) unvented vacutainer blood specimens, (9) 24-hour urines or other large volume specimens, (10) blood culture bottles (can be sent in tube carriers with waffle padding).

If the system is contaminated, PPD will close the system for decontamination. In the event that the system is down, the unit must make alternate arrangements for transporting specimens to the laboratory. Problems should be reported to PPD at 3-6281.

For Providers

Clinical Laboratory Improvement Act: Pre-Analytical Factors Affecting Laboratory Results Emphasis: Phlebotomy

Suggested Order of Draw Using an Evacuated Tube System and Order of Transfer From a Syringe to Sample Tubes

Julie C. Paulson Happel, M.T. (ASCP), M.A.
Photographs by Joel Carl, M.A.
Peer Review Status: Internally Peer Reviewed

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1. Blood culture tube
2. Plain tube, non-additive (e.g., red stopper)
3. Coagulation tube (e.g., blue stopper)
4. Additive tubes:
    a. Gel separator tube (e.g., black/red speckled stopper)
    b. Heparin (e.g., green stopper)
    c. EDTA (e.g., lavender stopper)
    d. Other additive tubes (e.g., oxalate/fluoride gray stopper)

Note:

1. When transferring blood from a syringe to evacuated tubes, place the tube(s) in a tube holder or rack. Do NOT handhold a tube while you are pushing the needle through the stopper. As soon as the needle is penetrated the stopper, it is fine to hold the tube in your hand. Alternatively, use a safety-syringe shielded transfer device.

2. Do NOT place any pressure on the syringe plunger when transferring blood from a syringe to evacuated tubes. The tube's vacuum will provide the negative pressure to pull the blood into the tube. Excess pressure may cause hemolysis.

3. The most current NCCLS standard states that if a coagulation tube is for APTT or PT only, the first tube drawn may be used for testing. However if special coagulation testing (e.g. Factor VIII) is being drawn, the second or third tube should be used. (A plain tube may be drawn and discarded if the special coagulation tests are the only tests being drawn.)

Section Top | Title Page

See related Provider Textbooks about Pathology.

See related Provider Topics Bones, Joints and Muscles, Ergonomics, Laboratory Tests, Pathology, Procedures and Therapies, Safety or Wellness and Lifestyle.

See related Patient Textbooks about Pathology.

Blood Collection Tubes / Order of Draw

Vacuum tubes with color coded stoppers indicating the anticoagulant contained are used for blood sample collections. In the **Alphabetical Test List**, the color-coding is indicated as well as the volume of blood sample required.

When collecting blood samples it is important to allow the tube to fill completely and to follow the "order of draw" for tubes as indicated in the guidelines of the National Committee for Clinical Laboratory Standards (NCCLS) and summarized in the following chart:

ORDER OF DRAW	COLOR OF STOPPER	DRAW VOLUME (mL)	COMMENTS
1	Blood Culture Collection Bottle		When a culture is ordered along with any other blood work, the blood cultures MUST be drawn first.
2	Yellow (SPS)	**10.0**	Contains Sodium polyanethol sulfonate, and is used to collect whole blood samples for blood culture AFB specimens. When a culture is ordered along with any other blood work, the blood cultures MUST be drawn first.
3	Plain Red	**3.0** **5.0** **7.0** **10.0**	Contains no additive. Do not mix or invert. Used for serum test(s), which cannot be collected in SST tubes.
4	Light Blue	**1.8** **2.7** **.5**	Referred to as Blue Top tube. Contains Sodium Citrate anticoagulant. Invert gently 8-10 times immediately after collection to prevent clotting. The correct proportion of blood to anticoagulant is critical for accurate results. Ensure tube is filled properly. Used mainly in coagulation studies.
5	(SST) Red/Gray ***or*** Gold Plastic Cap	**2.5** **4.0** **6.0**	Throughout this Guide, we refer to this as SST. Most commonly used tube where serum is required. Contains a gel separator and clot activator. Invert gently 5 times, allow clotting 30 minutes then centrifuging 10 minutes at 3000 Gs. After centrifugation, the gel forms a barrier between the clot and the serum. Tubes can be transported with no further preparation or handling. Transport tube in upright position.
6	Royal Blue	**7.0**	Contains Sodium Heparin anticoagulant Invert gently 8-10 times immediately after

8			
9	Lavender	**3.0** **5.0** **7.0**	Contains EDTA anticoagulant. Invert gently 8-10 times immediately after collection to prevent clotting. Complete filling of the tube is necessary for accurate results. 3 and 5 mL tubes are used for hematology, hemoglobin electrophoresis and Hemoglobin A_1c. The 7 mL tube is used for Red Cross specimen collections only.
10	Pale Yellow (ACDA)	**5.0** **8.5**	Contains Acid Citrate Dextrose Solution 'A' and is used primarily for Flow Cytometry testing. Invert gently 8-10 times immediately after collection to prevent clotting. Complete filling of the tube is necessary for accurate results.
11	Pale Yellow (ACDB)	**6.0**	Contains Acid Citrate Dextrose Solution 'B' and is used primarily for Bone Marrow Donor Registry. Invert gently 8-10 times immediately after collection to prevent clotting. Complete filling of the tube is necessary for accurate results.
11	Gray	**1.5** **3.0**	Not stocked by CLS Community Collection Sites, but is stocked in Acute Care locations. Contains Sodium Fluoride and Potassium Oxalate anticoagulant. Invert gently 8-10 times immediately after collection to prevent clotting. Complete filling of the tube is necessary for accurate results. Used primarily for lactate testing.

Types of Blood Samples

Serum:

Enough blood should be drawn to give the volume of serum required. A completely filled 4 mL serum separator tube (SST) will yield an average of 1.5 mL serum. A 10 mL SST yields 2.0-2.5 mL serum. Allow the blood to clot and separate the serum within two hours by centrifugation. Avoid hemolysis.

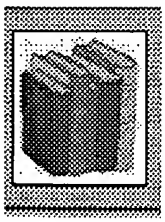
Plasma:

Use the proper anticoagulant (color-coded stoppers). Sufficient blood should be drawn to give the plasma volume requested. Mix gently but well. Centrifuge and separate the plasma within two hours of collection. Avoid hemolysis and inclusion of any erythrocytes in the plasma.

Whole Blood:

Use the proper anticoagulant. Mix gently but well. Do not centrifuge.

	(Green Band on Label)		collection to prevent clotting. Complete filling of the tube is necessary for accurate results. This tube is required for collection of **trace elements.**
7	Dark Green	**3.0** **7.0**	Contains Sodium Heparin anticoagulant. Invert gently 8-10 times immediately after collection to prevent clotting. Complete filling of the tube is necessary for accurate results.
	(PST) Light Green (mint) Green/gray	**3.0** **4.0** **5.0** **6.0**	Contains Lithium Heparin anticoagulant as well as a gel separator. Invert gently 8-10 times immediately after collection to prevent clotting. Complete filling of the tube is necessary for accurate results. Centrifuge 10 minutes at 3000 Gs. After centrifugation, the gel forms a barrier between the blood cells and the plasma. Tubes can be transported with no further preparation or handling. Transport tube in upright position.



Order of Draw—Facts and Controversies

Newsletter March 2002

Contents

The order of draw is often a mystery for many phlebotomists. It has changed over the years with little fanfare, and now that phlebotomy has evolved into a more recognized profession and acknowledgment over the significance of pre-analytical errors come to the forefront of our minds, we take another look at the facts and controversy surrounding the order of draw.

The NCCLS "...order of draw, which is recommended when drawing several specimens during a single venipuncture, is based on pragmatism."

1. Blood Culture tubes
2. Plain tube (non-additive)
3. Coagulation tube
4. Additive tubes
    a. Gel separator tube (serum)
    b. Heparin
    c. EDTA
    d. Oxalate/fluoride

Confusion seems to stem from three areas.

1. Syringe draws
2. SST placement in the order of draw
3. microcontainer collection

At one time blood collected using a syringe method had an alternate order of draw than that of the vacuum system. This is no longer the case. NCCLS recommends following the same order of draw for syringe draws and evacuated tube draws. This is reflected in the June 1998 NCCLS Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard Fourth Edition. This is also supported by popular literature in the field including the Phlebotomy Handbook Blood Collection Essentials by Diana Garza and Kathleen Becan-McBride in their new 6th edition phlebotomy text.

The serum separator tube is now considered an additive tube. It is correct to consider the SST as an additive tube since it contains a clot activator, usually silica or ground glass particles. According to NCCLS "Gel separator tubes are considered an additive tube but should be collected before other additive tubes because of the potential for additive contamination."

Some facilities and phlebotomists contend that the SST could or should be drawn prior to the blue top, or Na Citrate tube. One clinic did their own study on the effects of cross contamination of the SST to the NA Citrate tube to substantiate their claims that drawing the SST prior to the blue top tube would not cause adverse reactions in

the test results.

It should be noted that when a facility decides to establish procedures contrary to the national standard that they risk certain liabilities. A full scale study, as that done by the clinic, should be well documented to establish why the deviation should be acceptable.

During the time that NCCLS was considering this change there was an influx of phlebotomy text books that came out around the same time. They were operating under the old guidelines, unaware of the new changes coming out in 1998. Coupled with the fact that the maker of the most popular brand of tubes, BD, had not changed the order of draw at that time either, there was a great deal of confusion about the placement of the SST tube. Since, BD had changed their advertised order of draw to match that of NCCLS, drawing the same conclusion about the SST being an additive tube.

When discussing the order of draw for a microcollection we find that there is a difference. The reason for the difference is that the blood from a skin puncture will begin to clot and time is a factor to consider in keeping the specimen viable. According to NCCLS, EDTA specimens should be drawn first to ensure adequate volume and accurate hematology test results. Other additive specimens are next and serum specimens are last. The only deviation from the order of draw that is the accepted standard is with the microcollection. Because there is a deviation causes some confusion, but understanding the reasoning behind it should help to clarify confusion and remind phlebotomists of the importance of knowing the order of draw, and the additive in any given tube.

Microcollection Order of Draw

EDTA
Additive tubes for whole blood
Serum tubes

It is important to remember that the order of draw is designed to prevent cross contamination that can result in erroneous lab results. Anytime a pre-analytical error is introduced to a specimen that specimen is affected. A specimen is the biological representation of a patient. If we leave the tourniquet on too long, we don't use the proper order of draw, we let the cells sit unspun too long, we hemolyze the sample, or we do any other of the multitude of possible errors that can be done to a specimen, we change the biological make up of that specimen and it no longer is a true representation of the patient who has entrusted us to take proper care of them. Every standard that we are expected to employ as phlebotomists to obtain or process a specimen is based on logic, knowledge and study. Something as seemingly simple and undetectable as changing the order of draw during the procedure can create a change in the representation of that specimen. Care and consideration of the proper order of draw is significant to good patient care.

Alliance Laboratory Services

Health Alliance™

Order of Draw for Blood Specimens

Purpose:

Quality control and accurate test results begin with patient preparation and sample collection. Following the recommended order of draw for blood specimens is important for specimen integrity.

When collecting several tubes of blood, one must follow an "order of draw" to diminish the possibility of cross contamination between tubes due to the different additives present. Errors in the "order of draw" can affect chemistry and hematology results.

The National Committee of Clinical Laboratory Standards (NCCLS) has set guidelines concerning the correct procedures for collecting and handling blood specimens.

Procedure:

A. Evacuated Tube Method

When drawing multiple vacutainer tubes during a single venipuncture the following order of draw should be followed:

Tube Type	Additive
1. Blood Culture - Aerobic	Sterile Specimen
2. Blood Culture - Anaerobic	Sterile Specimen
3. Red	None
4. Light Blue*	Sodium Citrate
5. Serum Separator (SST)	None (does contain clot activator)
6. Green or Green/Gray	Heparin
7. Lavender	EDTA
8. Gray	Sodium Fluoride/Potassium Oxalate
9. Yellow	ACD

*If drawing a blue top tube for coagulation tests, (other than PT and PTT), a red top tube (2-3 cc) must be drawn first to avoid contamination from tissue thromboplastin, which can yield false coagulation results. Blue top tubes must also be completely filled to avoid erroneous test results.

B. Syringe Method

1. Blood Cultures
2. Other sterile tubes
3. Light blue
4. SST
5. Green
6. Lavender
7. Gray
8. Yellow
9. Red

C. Microtainer Collection Method

If multiple specimens are to be collected by skin puncture (heel or fingerstick), anticoagulant tubes must be collected first to avoid microclots from forming because of a prolonged collection.

1. Blood gases
2. Slides/smears
3. EDTA tubes
4. Other additive tubes
5. Serum tubes

D. Errors

1. Anticoagulant cross contamination

    a. Citrate Tissue thromboplastin can yield false coagulation results if drawn first. (Except when drawing PT & PTT)